



**[Billing Code 4140-01-P]**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Laboratory Animal Welfare: Report on Reducing Administrative Burden for  
Researchers: Animal Care and Use in Research**

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice

**SUMMARY:** The National Institutes of Health (NIH) is announcing the publication of Reducing Administrative Burden for Researchers: Animal Care and Use in Research, a report by the NIH, the United States Department of Agriculture (USDA), and the Food and Drug Administration (FDA). The report describes the recommendations of the 21st Century Cures Act, Section 2034(d), Working Group and decisions of the agencies.

**FOR FURTHER INFORMATION CONTACT:** Patricia Brown, Office of Laboratory Animal Welfare (OLAW), Office of Extramural Research, National Institutes of Health, Suite 2500, 6700B Rockledge Drive, Bethesda, MD 20892-6910, phone: 301-496-7163, email: [olaw@od.nih.gov](mailto:olaw@od.nih.gov).

**SUPPLEMENTARY INFORMATION:**

## **I. Background**

Title II, Section 2034(d) of the 21st Century Cures Act (Pub. L. 114-255) was enacted December 13, 2016, and requires the NIH in collaboration with USDA and FDA to complete a review of applicable regulations and policies for the care and use of laboratory animals and to make revisions, as appropriate, to reduce administrative burden on investigators while maintaining the integrity and credibility of research findings and protection of research animals. The Act instructs NIH to: (1) seek the input of experts, if appropriate; (2) identify ways to ensure applicable regulations and policies are not inconsistent, overlapping, or unnecessarily duplicative; (3) take steps to eliminate or reduce identified inconsistencies, overlap, or duplication among such regulations and policies; and (4) take other actions, as appropriate, to improve the coordination of regulations and policies with respect to research with laboratory animals.

NIH, USDA, and FDA convened a Working Group of federal subject matter experts to identify inconsistent, overlapping, and unnecessarily duplicative regulations and policies and prepare a report of their recommendations as directed in the 21st Century Cures Act. The report on Reducing Administrative Burden for Researchers: Animal Care and Use in Research describes the efforts of the Working Group, their recommendations, and the decisions of NIH, USDA, and FDA on the recommendations.

## **II. Electronic Access**

The report on Reducing Administrative Burden for Researchers: Animal Care and  
Use in Research is available at

[https://olaw.nih.gov/sites/default/files/21CCA\\_final\\_report.pdf](https://olaw.nih.gov/sites/default/files/21CCA_final_report.pdf).

Dated: August 21, 2019.

---

Francis S. Collins,

Director,

National Institutes of Health.

[FR Doc. 2019-18611 Filed: 8/27/2019 8:45 am; Publication Date: 8/28/2019]